

**Prepared Testimony of the
Honorable Tom A. Coburn, M.D.
Before the Subcommittee on Criminal Justice,
Drug Policy and Human Resources**

“Cervical Cancer and Human Papillomavirus”

March 11, 2004

Chairman Souder, Ranking Member Cummings, distinguished members of the Subcommittee, I am grateful for the opportunity to address the Subcommittee regarding cervical cancer and human papillomavirus (HPV). I commend the Subcommittee for its continued efforts to promote awareness about HPV and cervical cancer.

Observations from My Medical Practice

I am a practicing physician and a member of the American Academy of Family Physicians and the American Academy of Otorhinolaryngology. I have been practicing medicine for 18 years. My patients represent a broad segments of the population, including those covered under Medicaid and Medicare.

During my nearly two decades treating patients I have seen an every growing number affected by sexually transmitted diseases. In particular, I have been performing an increasing number of procedures to treat HPV infection.

I want to relate to you the story of one recent patient of mine. She is an 18-year-old girl who has had only one sexual partner. She is now infected with HPV. To prevent the onset of invasive cervical cancer, a large portion of this young girl's cervix had to be removed. As a result she is less likely to be able to become pregnant in the future and more likely to have a premature infant if she does become pregnant. And despite already undergoing invasive treatment, she remains at risk for future complications and additional surgeries.

This girl and the others that I am caring for every day in my medical practice are the real faces of those affected by HPV. What we are confronting is not an isolated epidemic.

The National HPV Epidemic

HPV is the most common sexually transmitted disease in the United States. About 24 million Americans are currently infected with HPV according to the National

Cancer Institute and an estimated 5.5 million Americans become infected with HPV every year. With 4.6 million of these HPV infections acquired by those aged 15 to 24, HPV accounts for over half of all new sexually transmitted diseases among young Americans. On March 8, 2004, researchers from the Colorado Health Sciences Center reported that more than 30 percent of women in a recent study were found to be infected with a strain of HPV linked to cervical and anal cancer. In comparison, 18.7 percent of men carried HPV-16, one of 10 high-risk strains of the virus.

Over 1,350,000 women will have invasive procedures each year just to assess the status of their abnormal pap smears secondary to HPV. According to the American Cancer Society, every year over 12,000 new cases of invasive cervical cancer are diagnosed and more than 4,000 women die of the disease. And non-invasive cervical cancer is estimated to be four times as widespread as the invasive type.

HPV is also associated with oral cancer, cancers of the vagina, penis, anus, head and neck, more than one million pre-cancerous lesions, and genital warts. In addition, HPV has been detected in some prostate tumors. An infected mother may transmit HPV to her newborn with affected children facing prolonged, difficult treatment for respiratory papillomatosis.

Federal Health Agencies Ignore Scientific Data

During my tenure in Congress (1995- 2001), I heard from other practicing physicians all across the nation confronting the same epidemic of HPV and other STDs that I was seeing in my own medical practice. Few of my patients with HPV, or the patients of my colleagues, had ever heard of the virus and were unaware of its health risks.

A growing library of scientific data demonstrated that HPV was linked to a number of serious health conditions, with over 99 percent of all cervical cancers associated with HPV infection.

Likewise, scientific data concluded that condoms provided no protection against HPV infection. “Behaviors such as beginning sexual intercourse at an early age-- especially age 16 or younger-- and having many sexual partners increase the chance that a woman will develop an HPV infection in the cervix,” according to the National Cancer Institute. Those with multiple sexual partners or who had partners with multiple sexual partners enhance their risk for pervasive HPV infection by increasing the likelihood of exposure to HPV, as well as repeated exposure and re-infection, regardless of condom use.

Therefore, those who chose to have multiple sexual partners believing they were being protected by following the advice of the Centers for Disease Control and Prevention (CDC) to use condoms, were actually placing themselves and their partners at increased risk for HPV infection.

Studies had indicated for years that promiscuity was associated with cervical cancer and that contrary to CDC dogma, condoms did not protect against the cervical cancer virus. Then an April 1- 3, 1996 National Institutes of Health Consensus Development Conference Statement on Cervical Cancer stated “Primary prevention of HPV infection will require (1) directing education efforts toward adolescents and health care providers regarding the strong causal link between acquisition of HPV as a sexually transmitted disease and development of cervical cancer and its precursors, (2) encouraging delayed onset of sexual intercourse, (3) developing an effective prophylactic vaccine, and (4) developing effective vaginal microbicides. The data on the use of barrier methods of contraception to prevent the spread of HPV is controversial but does not support this as an effective method of prevention.”

Regardless of these scientific findings and recommendations, the CDC ignored the NIH consensus statement and continued to focus almost exclusively on promoting condom use and regular PAP tests.

As a family physician/obstetrician, I cannot understate the importance of regular PAP test for women and I support federal efforts that encourage and provide access to such tests.

As an HPV prevention message, however, this approach was designed to fail, as it has. Promoting condom use did nothing to control the rampant spread of HPV since condoms cannot prevent HPV infection. PAP tests and treatment certainly are responsible for the dramatic decline in cervical cancer deaths, but likewise do not and cannot prevent HPV infection. CDC has confused disease management with disease prevention.

Treatment is often invasive, unpleasant, and costly and does not preclude the necessity for additional treatments or adverse side effects.

Cervical cancer is treated using surgery, radiation and chemotherapy; sometimes two or more methods are used. The most common types of surgery include cryosurgery, laser surgery, cone biopsy, simple hysterectomy, radical hysterectomy and pelvis lymph node dissection, and pelvic exenteration. Radiation therapy may involve external radiation or internal radiation (radioactive materials implanted in the tumor).

Treatment for cervical dysplasia—a premalignant or precancerous change in the cells of the cervix that may progress to cancer—include surgery, cone biopsy, cryosurgery, laser surgery, and electrosurgery.

The direct medical cost of treating a patient with cervical cancer is \$9,200 to \$13,360, while surgery to remove a precancerous lesion is \$1,100 to \$4,360. The financial burden of HPV in the U.S. has been estimated to range from \$1.6 billion to \$6 billion annually, making HPV one of the most costly sexually transmitted diseases after HIV/AIDS.

It is a cruel distortion of the word “prevention” to tell women and young girls that the tremendous physical, emotional and financial costs of treatment for HPV infection are a cost worth bearing as a consequence of federal health agencies intentional distortion and cover-up of scientific data related to HPV.

Armed with personal stories of women suffering the physical and emotional consequences of HPV infection from my own medical practice and supported by the best available scientific data, I repeatedly asked the CDC and the Food and Drug Administration (FDA) to take action to educate the public about HPV. Yet both CDC and FDA continued to maintain that condoms do prevent HPV or that perhaps more research was necessary to determine what level of protection condoms do provide.

In a February 19, 1999 letter to the House Commerce Committee on which I served, Dr. Richard D. Klausner, then-Director of the National Cancer Institute (NCI), stated, “condoms are ineffective against HPV.” The science in this regard is so clear that Dr. Klausner concluded “additional research efforts by NCI on the effectiveness of condoms in preventing HPV transmission are not warranted.”

On March 16, 1999, the House Commerce Committee’s Subcommittee on Health and the Environment held a hearing entitled “Women’s Health: Raising Awareness of Cervical Cancer.” At this hearing, CDC continued to argue that condom use does protect against HPV. When asked in a follow up letter to NCI to “explain the difference in conclusions made by CDC and NCI,” Dr. Douglas Lowy, Deputy Director of NCI’s Division of Basic Sciences, explained that “the NCI conclusion that condoms are ineffective against HPV infection is based on the results of several long term studies that have failed to show that barrier contraceptives prevent cervical HPV infection, dysplasia, or cancer.” NCI provided a number of published studies to support this lack of protection but was unable to explain CDC’s claims, suggesting that perhaps CDC had confused HPV with HIV.

When the expert testimony of the Nation’s premier health agency and published scientific data still failed to convince CDC and FDA that condoms do not protect against HPV, I asked Dr. Klausner to convene a panel of experts to review the available data and issue a consensus statement. On June 12-13, 2000, in Herndon, Virginia, representatives from the National Institute of Allergy and Infectious Diseases, FDA, CDC and the U.S. Agency for International Development gathered to evaluate the published data on latex condoms and STD prevention.

The panel’s report entitled “Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention” issued in April 2001 “concluded that there was no evidence that condom use reduced the risk of HPV infection.” The panel, furthermore, found that based on a meta-analysis of published studies, condoms could reduce the risk of HIV infection for men and women and the risk of gonorrhea for men only. In regards to the remaining STDs, the panel concluded “there was insufficient evidence from the epidemiological studies on these diseases to draw definite conclusions

about the effectiveness of the latex male condom in reducing the transmission of these diseases.”

Yet a month after the release of the panel’s report, the CDC website posted a fact sheet entitled “Condoms and Their Use in Preventing HIV and Other STDs” that read “The correct and consistent use of latex condoms during sexual intercourse- vaginal, anal, or oral- can greatly reduce a person’s risk of acquiring or transmitting most STDs, including HIV infection, gonorrhea, chlamydia, trichomonas, human papilloma virus infection (HPV), and hepatitis B.”

The Passage of a Federal HPV Law

With my pleas ignored, I authored legislation directing the CDC and FDA to take actions to educate the public with “medically accurate information” about HPV. I was disappointed when groups that claimed to advocate for women’s health, such as the American College of Obstetricians and Gynecologists (ACOG), opposed my proposal and fought to keep the public misinformed about HPV.

The HPV law was approved by Congress as a component of the Consolidated Appropriations Act of 2001 and became Public Law 106-554 with the signature of President Bill Clinton on December 21, 2000. In a Statement of Administration policy, President Clinton stated, “The Administration supports the goal of better informing the public about HPV and the fact that the use of condoms may not fully prevent HPV transmission.”

The law directed CDC to develop a report outlining the “best strategies to prevent future infections, based on the available science.” CDC was also directed to conduct a number of studies to determine the prevalence of specific types of HPV infection in various regions of the U.S., the impact of HPV diagnosis on patients, the level of HPV knowledge of physicians and the public. Upon the completion of these studies, CDC is to “develop and disseminate educational materials for the public and health care providers regarding HPV and its impact and prevention.”

The law directs the FDA to “reexamine existing condom labels ... to determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including HPV.”

Finally, the law requires that all educational and prevention material printed by the Department of Health and Human Services (HHS), CDC, FDA, and other HHS agencies, contractors, grantees and subgrantees “that are specifically designed to address STDs including HPV shall contain medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing the STD the materials are designed to address.”

Enactment of the Law

I quickly learned that it would require more than passing a law to convince CDC and FDA to take action to educate the public about HPV.

The law is clear that the CDC and other government agencies and partners must provide “medically accurate information regarding the effectiveness or lack of effectiveness of condoms” in preventing HPV and other sexually transmitted diseases. Yet in a July 2001 “Dear Colleague” letter to its partners, the CDC issued inaccurate information regarding the effectiveness of condoms. The CDC stated “epidemiological studies have generally not demonstrated an association between condom use and the risk of HPV infection, but these studies are inconclusive because of limitations in how they were designed. Again, these limitations would generally lead to an underestimation of the protective effect.” The inaccurate claim that studies are “inconclusive” is repeated several times in the CDC letter. The CDC letter also provides what is labeled “Theoretical Basis for Protection” that claims “consistent and correct use of latex condoms would be expected to protect against transmission of genital ulcer diseases and HPV in some, but not all, instances.” This is medically inaccurate and does not reflect the available clinical science.

A progress report was required to be made to Congress within a year of enactment of this law, which would have been December 21, 2001. The report, dated “August 2003,” was delivered to Congress on September 12, 2003, nearly two years overdue.

The CDC was required by law to “develop a final report not later than three years after such effective date [before December 21, 2003], including a detailed summary of the significant findings and problems and best strategies to prevent future infections, based on the available science.” CDC released a timetable in September 2003 projecting that this report would not be released in compliance with the legally sanctioned date, but rather in 2007, four years after the due date set by law.

Congress approved the HPV law precisely because federal health agencies had failed to educate the American public about the health risks of HPV and how it can be prevented and now these same agencies were continuing their cover-up of the HPV epidemic, now in violation of federal law.

Because of this continued resistance, I requested the Inspector General of the Department of Health and Human Services “conduct a thorough investigation to determine why Public Law 106-554 has been both misinterpreted and largely ignored by CDC and the FDA and to make recommendations to ensure that these agencies immediately comply with the directives and intent of this law” and to “determine if federal agencies and organizations receiving federal funds are providing medically accurate information about HPV.”

But only after pressure was applied to CDC by this Subcommittee and other Congressional offices, did the agency finally issue the HPV prevention report on January 30, 2004, a month past the deadline set by law.

The CDC report, entitled “Report to Congress: Prevention of Human Papillomavirus Infection” finally acknowledges that the CDC’s long held positions on HPV and condoms were incorrect. Specifically, the CDC report states:

“Because genital HPV infection is most common in men and women who have had multiple sex partners, abstaining from sexual activity (i.e. refraining from any genital contact with another individual) is the surest way to prevent infection. For those who choose to be sexually active, a monogamous relationship with an uninfected partner is the strategy most likely to prevent future genital HPV infections. For those who choose to be sexually active but who are not in a monogamous relationship, reducing the number of sexual partners and choosing a partner less likely to be infected may reduce the risk of genital HPV infection. ...

“The available scientific evidence is not sufficient to recommend condoms as a primary prevention strategy for the prevention of genital HPV infection. ...

“Regarding other possible prevention approaches, no data indicate that treatment of clinical lesions or use of microbicides will prevent transmission of infection.”

The FDA has yet to act to ensure that condom labeling is medically accurate to reflect the lack of effectiveness of condoms in preventing HPV infection as required by the law. The FDA’s failure to inform consumers about the lack of effectiveness of condoms in preventing HPV undermines that agency’s mission of ensuring that products are safe and effective.

Recommendations

Continued oversight by this Subcommittee is essential to ensure that CDC and FDA fully comply with the federal HPV prevention and education law and to ensure that the public is given medically accurate information about HPV.

With 4.6 million young people under the age of 25 expected to contract this disease, more than 4,000 women projected to die as a result of cervical cancer and up to \$6 billion to be spent on HPV care all within a single year, turning back the HPV epidemic should be among the highest of CDC’s priorities. CDC must take immediate action to aggressively promote the findings and prevention recommendations contained within its January 2004 HPV prevention report. This includes promoting the value of delaying sexual debut and avoiding promiscuity. Recent studies have found that young Americans are ready to hear this message and are already choosing abstinence. *The New York Times* reported on March 7, that “More than half of all male high school students reported in 2001 that they were virgins, up from 39 percent in 1990.” The trends are

similar for female students, who are even more likely than boys to report that they are virgins, according to the data reported in the *New York Times*.

In addition to efforts to support healthy behaviors, Congress and the National Institutes for Health should continue to support the research and development of an effective HPV vaccine.

Finally as a physician I believe that the history of stonewalling, cover-up and erroneous statements regarding HPV put forth by CDC and FDA over the past decade have compromised these agencies' credibility and endangered the public's health. This is unfortunate since so many look to these agencies for sound scientific advice and guidance.

I thank this Subcommittee for its continued leadership in protecting the public's health by ensuring that science is not manipulated, suppressed or distorted to advance a political rather than public health agenda.

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